

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

JUDITH GODINEZ, Individually and on
Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ALERE INC., *et al.*,

Defendants.

Civil Action No. 1:16-cv-10766-PBS

LEAVE TO FILE GRANTED

MARCH 22, 2017 (DKT. NO. 85)

**PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE
SUPPLEMENTAL AND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT**

TABLE OF CONTENTS

	Page
PRELIMINARY STATEMENT	1
SUMMARY OF FACTS	4
Defendants	4
Alere Assured Investors of the Adequacy of Internal Controls Despite Ample Internal Evidence That Those Representations Were False	5
Defendants Set Up Alere for Sale and a Multi-Million Dollar Payday for Nawana and Hinrichs	6
INRatio’s Recall Becomes Likely by the Fourth Quarter of 2015	6
Alere Announces Abbott’s Agreeing to Buy Alere	7
Alere is Unable to Timely File Its 2015 Form 10-K Throwing its Merger With Abbott into a State of Uncertainty	8
Alere Recalls INRatio and Then Discloses Knowing of Those Facts in 2015	9
Alere Files its 2015 10-K and Discloses That Internal Control Weaknesses Have Still Not Been Effectively Resolved	9
Alere’s Operating Units Face Dire Regulatory Scrutiny	10
Abbott and Alere Litigate Over the Merger.....	12
Alere is Unable to Timely File 2016 Its Form 10-K and Is Forced to Disclose New Revenue Errors From 2015	14
ARGUMENT	14
I. PLAINTIFFS HAVE ALLEGED FACTS GIVING RISE TO A STRONG INFERENCE THAT DEFENDANTS ACTED WITH SCIENTER.....	14
A. The Total Mix of Information Supports a Strong Inference of Scienter.....	15
B. The Individual Defendants’ Motive to Personally Profit from Alere’s Sale Supports a Strong Inference of Scienter	17
C. Defendants’ Efforts to Hide Key Facts From Abbott Also Supports a Strong Inference of Scienter	19

D. The Materiality of Defendants’ Misrepresentations Support a Strong Inference of Scienter22

E. The Simple and Obvious Nature of Alere’s GAAP Violations Supports a Strong Inference of Scienter26

F. Red Flags and Widespread Knowledge at Alere Relating to Internal Control Issue Also Support a Strong Inference of Scienter28

G. Plaintiffs Allege a Strong Inference of Scienter With Respect to the FCPA Violations Which are Tied to the Lack of Internal Financial Controls.....31

H. Defendants Admit that the Facts Giving Rise to INRatio’s Recall Were Present as of December 2015.....33

I. Plaintiffs Also Allege a Strong Inference of Scienter with Respect to Alere’s Billing Practices36

II. PLAINTIFFS PROPERLY ALLEGE CLAIMS ARISING FROM DEFENDANTS’ STATEMENTS RELATING TO THE ABBOTT MERGER.....38

CONCLUSION.....40

TABLE OF AUTHORITIES

Cases	Page(s)
<i>AES Puerto Rico, L.P. v. Trujillo-Panisse</i> , 133 F. Supp. 3d 409 (D.P.R. 2015).....	20
<i>Akerman v. Arotech Corp.</i> , 608 F. Supp. 2d 372 (E.D.N.Y. 2009)	34
<i>Aldridge v. A.T. Cross Corp.</i> , 284 F.3d 72 (1st Cir.2002).....	15, 28
<i>Anderson v. Spirit AeroSystems Holdings, Inc.</i> , 827 F.3d 1229 (10th Cir. 2016)	22
<i>Aronson v. Advanced Cell Tech, Inc.</i> , 972 F. Supp. 2d 123 (D. Mass. 2013)	20
<i>Blatt v. Muse Techs., Inc.</i> , 2002 U.S. Dist. LEXIS 18466 (D. Mass. Aug. 27, 2002)	25
<i>Chalverus v. Pegasystems, Inc.</i> , 59 F. Supp. 2d 226 (D. Mass. 1999)	17
<i>City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.</i> , 632 F.3d 751 (1st Cir. Mass. 2011)	22
<i>Cody v. Conformix, Inc.</i> , 2016 U.S. Dist. LEXIS 101754 (D. Mass. Aug. 3, 2016)	30
<i>Collier v. ModusLink Glob. Sols., Inc.</i> , 9 F. Supp. 3d 61 (D. Mass. 2014)	30
<i>Crowell v. Ionics, Inc.</i> , 343 F. Supp. 2d 1 (D. Mass. 2004)	22, 24
<i>ECA, Local IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.</i> , 553 F.3d 187 (2d Cir. 2009).....	26
<i>Fait v. Regions Fin. Corp.</i> , 655 F.3d 105 (2d Cir. 2011).....	34
<i>Foman v. Davis</i> , 371 U.S. 178 (1982).....	40

<i>Frank v. Dana Corp.</i> , 646 F.3d 954 (6th Cir. 2011)	16
<i>Ganino v. Citizens Utils. Co.</i> , 228 F.3d 154 (2d Cir. 2000).....	22, 24, 26
<i>Garber v. Legg Mason Inc.</i> , 347 Fed. Appx. 665 (2d Cir. 2009).....	18
<i>Gerber v. Bowditch</i> , No. 05-10782-DPW, 2006 U.S. Dist. LEXIS 27552 (D. Mass. May 8, 2006).....	39
<i>Glassman v. Computervision Corp.</i> , 90 F.3d 617 (1st Cir. 1996).....	26
<i>Greebel v. FTP Software, Inc.</i> , 194 F.3d 185 (1st Cir. 1999).....	27
<i>Halford v. AtriCure, Inc.</i> , 2010 WL 8973625 (S.D. Ohio Mar. 29, 2010).....	33
<i>In re Apollo Grp., Inc. Sec. Litig.</i> , 2011 U.S. Dist. LEXIS 124781 (D. Ariz. Oct. 27, 2011).....	35
<i>In re ARIAD Pharm., Inc. Secs. Litig.</i> , 842 F.3d 744 (1st Cir. 2016).....	30
<i>In re Bear Stearns Cos. Inc. Sec Deriv. & ERISA Litig.</i> , 763 F. Supp. 2d 423 (S.D.N.Y. 2011).....	39
<i>In re Bristol-Meyers Squibb Sec. Litig.</i> , 312 F. Supp.2d 549 (S.D.N.Y. 2004).....	19, 33
<i>In re Cabletron Sys. Inc.</i> , 311 F.3d 11 (1st Cir. 2002).....	<i>passim</i>
<i>In re Cobalt Int’l Energy, Inc. Sec Litig.</i> , 2016 U.S. Dist. LEXIS 5702 (S.D Tex. Jan 19, 2016).....	34
<i>In re Ebix, Inc. Secs. Litig.</i> , 898 F. Supp. 2d 1325 (N.D. Ga. 2012).....	29
<i>In re Enron Corp. Sec. Derivative & ERISA Litig.</i> , 235 F. Supp. 2d 549 (S.D. Tex. 2002)	17, 33

<i>In re Gentiva Sec. Litig.</i> , 932 F. Supp. 2d 352 (E.D.N.Y. 2013)	33-34
<i>In re Hutchinson Tech. Inc. Sec. Litig.</i> , 502 F. Supp. 2d 884 (D. Minn. 2007).....	34
<i>In re Immucor Inc. Sec. Litig.</i> , 2006 U.S. Dist. LEXIS 72335 (N.D. Ga. Oct, 4, 2006).....	16
<i>In re Learnout & Hauspie Sec. Litig.</i> , 208 F. Supp. 2d 74 (D. Mass. 2002)	28
<i>In re Magnum Hunter Res. Corp. Sec. Litig.</i> , 26 F. Supp. 3d 278 (S.D.N.Y. 2014).....	30
<i>In re Manulife Fin. Corp. Sec. Litig.</i> , 276 F.R.D. 87 (S.D.N.Y. 2011)	32-33
<i>In re PerkinElmer, Inc. Sec. Litig.</i> , 286 F. Supp. 2d 46 (D. Mass. 2003)	26
<i>In re Raytheon Sec. Litig.</i> , 157 F. Supp. 2d 131 (D. Mass. 2001)	26, 28
<i>In re Salix Pharms., Ltd.</i> , 2016 U.S. Dist. LEXIS 54202 (S.D.N.Y. 2011).....	39
<i>In re Segue Software, Inc., Sec. Litig.</i> , 106 F. Supp. 2d 163 (D. Mass. 2000)	25
<i>In re Syncor Int’l Corp. Sec. Litig.</i> , 327 F. Supp. 2d 1149 (C.D. Cal. 2004) <i>aff’d in part, rev’d in part and remanded</i> , 239 F. App’x 318 (9th Cir. 2007)	33
<i>In re Turquoise Hill Res. Ltd. Sec. Litig.</i> , 2014 U.S. Dist. LEXIS 174096 (S.D.N.Y. Dec. 16, 2014)	31
<i>Karpov v. Insight Enters., Inc.</i> , 2010 U.S. Dist. LEXIS 59771 (D. Ariz. Apr. 30, 2010).....	30-31
<i>Local No. 8 IBEW Ret. Plan & Trust v. Vertex Pharms., Inc.</i> , 838 F.3d 76 (1st Cir. 2016).....	30
<i>LoConte v. Forest Labs., Inc., (Celexa & Lexapro Marketing & Sales Practices Litig.)</i> , 2015 U.S. Dist. LEXIS 77698 (D. Mass. June 15, 2015)	18

<i>Makor Issues & Rights, Ltd. v. Tellabs Inc.</i> , 513 F.3d 702 (7th Cir. 2008)	27
<i>Malone v. Microdyne Corp.</i> , 26 F.3d 471 (4th Cir. 1994)	27
<i>Matrixx Initiatives, Inc. v. Siracusano</i> , 563 U.S. 27 (2011).....	35
<i>Messner v. USA Techs., Inc.</i> , 2016 U.S. Dist. LEXIS 50132 (E.D. Pa. Apr. 13, 2016)	22
<i>Mississippi Pub. Employees' Ret. Sys. v. Boston Scientific Corp.</i> , 523 F.3d 75 (1st Cir. 2008).....	14-15
<i>N. Collier Fire Control & Rescue Dist. Firefighter Pension Plan & Plymouth Cnty. Ret. Ass'n v. MDC Partners, Inc.</i> , 2016 U.S. Dist. LEXIS 136929 (S.D.N.Y. Sept. 30, 2016).....	27-28
<i>N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.</i> , 537 F.3d 35 (1st Cir. 2008).....	18-19
<i>Roth v. OfficeMax, Inc.</i> , 527 F. Supp. 2d 791 (N.D. Ill. 2007)	31
<i>SEC v. Collins & Aikman Corp.</i> , 524 F. Supp. 2d 477 (S.D.N.Y. 2007).....	19, 32
<i>SEC v. Escala Grp., Inc.</i> , 2009 U.S. Dist. LEXIS 67225 (S.D.N.Y. July 31, 2009)	27
<i>Shaw v. Digital Equip. Corp.</i> , 82 F.3d 1194 (1st Cir. 1996).....	39-40
<i>Sloman v. Presstek, Inc.</i> , 2007 U.S. Dist. LEXIS 69475 (D.N.H. Sept. 18, 2007).....	15
<i>Tellabs, Inc. v. Makor Issues & Rights, Ltd.</i> , 551 U.S. 308 (2007).....	<i>passim</i>
<i>United States ex rel. Griffith v. Conn.</i> , 2015 U.S. Dist. LEXIS 22668 (E.D. Ky. Feb. 24, 2015).....	21
<i>U.S. v. Nacchio</i> , 519 F.3d 1140 (10th Cir. 2008)	26

<i>Varghese v. China Shenghuo Pharm. Holdings</i> , 672 F. Supp. 2d 596 (S.D.N.Y. 2009).....	29
<i>Van Noppen v. InnerWorkings, Inc.</i> , 136 F. Supp. 3d 922 (N.D. Ill. 2015)	24
<i>Washtenaw Cty. Employees Ret. Sys. v. Avid Tech., Inc.</i> , 28 F. Supp. 3d 93 (D. Mass. 2014)	16, 22, 32
<i>Washtenaw Cty. Employees’ Ret. Sys. v. Talbots, Inc.</i> , 2013 WL 5348569 (D. Mass. Sept. 23, 2013)	20
<i>W. Palm Beach Police Pension Fund v. DFC Glob. Corp.</i> , 2015 U.S. Dist. LEXIS 77495 (E.D. Pa. June 16, 2015)	36
<i>Zucco Partners, LLC v. Digimarc Corp.</i> , 552 F.3d 981 (9th Cir. 2008)	39
Statutes and Rules	
15 U.S.C. §78m(b) 2017	16, 29
Fed. R. Evid. 201(b).....	18

Lead Plaintiffs the Glazer Funds and Plaintiffs OFI Asset Management and NECA-IBEW Pension Trust Fund (collectively, “Plaintiffs”) respectfully submit this Opposition to Defendants’ Motion to Dismiss the Supplemental and Amended Consolidated Class Action Complaint (the “Complaint”).

PRELIMINARY STATEMENT

Alere, Inc. (“Alere” or the “Company”) has revealed itself to have among the most grossly deficient internal controls over financial reporting of any publicly-held company. Alere’s admitted material weaknesses in internal controls have caused it to miss filing its Form 10-Ks for two years in a row, restate its earnings, and subject it to numerous federal investigations (including criminal investigations), which have caused serious harm to its investors. Defendants managed to keep the Company’s abject lack of internal controls and other related material adverse facts hidden from investors long enough that on January 30, 2016, Abbott Laboratories (“Abbott”), without knowing these facts, agreed to acquire Alere for a premium price of \$56.00 per share.

Indeed, less than one month after Alere and Abbott announced their merger, on February 26, 2016, Defendants announced Alere was unable to timely file its 2015 Form 10-K with the Securities and Exchange Commission (“SEC”). By March 15, 2016, Defendants were forced to admit that the Company’s internal financial controls were so deficient that Alere would not file the 2015 Form 10-K anytime soon. By that time, Abbott was conducting due diligence of Alere relevant to its proposed acquisition of the Company, which enabled it to further determine the true extent of Alere’s undisclosed material problems. Abbott correctly sounded the alarm as to the severity of the underlying undisclosed material facts by seeking to avoid completing its merger with Alere, disclosing that Alere is not in fact the Company Abbott had originally agreed to buy, causing Alere’s stock to plummet.

Alere's internal financial controls proved so grossly deficient that Alere needed until August 2016 to file its 2015 Form 10-K and restated its earnings for prior periods, including 2015. That belated filing conceded that, even at that late date, Alere had not yet been able to resolve its financial control weaknesses and that, as a result, its publicly filed financial statements could not be relied upon. Indeed, Alere has also now been unable to timely file its 2016 Form 10-K with the SEC because of, *inter alia*, additional revenue reporting errors relating to the 2015 fiscal year. It is currently unknown whether Alere will have to restate, and withdraw reliance on, its previously issued financial statements.

Alere's conceded inadequacies in internal financial controls enabled the Company to artificially inflate its reported operating results and hide other material adverse facts from investors while preparing the Company to be bought out. Alere's belatedly-filed 2015 Form 10-K disclosed earnings restatements for previously-reported 2015 quarterly results based upon blatant violations of well-understood and straightforward generally accepted accounting principles ("GAAP") relating to revenue recognition. Each prior misstatement had portrayed the Company's operating results in a materially more favorable light than reality, even before Alere disclosed new additional errors in 2017 related to its reporting of 2015 revenues and profits that amounted to at least an additional \$5-10 million in errors. Declaration of Jeffrey S. Abraham ("Abraham Decl.") Ex. A.

Once Abbott agreed to acquire Alere, investors learned for the first time other material adverse facts concerning the Company's operations. These included: (i) Alere's recall of its key INRatio blood monitoring product; (ii) a federal investigation of Alere's potential violations of the anti-bribery provisions of the Foreign Corrupt Practices Act ("FCPA"); (iii) the Centers for Medicare and Medicaid Services' ("CMS") suspension of Alere's wholly owned subsidiary,

Arriva Medical LLC (“Arriva”), from U.S. government programs for seeking reimbursement for deceased patients; and (iv) a federal investigation of undisclosed billing problems at the Company’s toxicology unit. These material undisclosed facts resulted, at least in part, from Alere’s material weaknesses in internal controls, and their disclosure caused significant additional harm to Alere shareholders.

Contrary to Defendants’ arguments, this case does not involve mere “good faith accounting errors.” Instead, the facts show that Defendants have affirmatively kept material adverse facts from investors (including Abbott as part of the due diligence process). For example, throughout the due diligence of Alere, the Company denied Abbott access to general ledgers designed to track overseas payments for compliance with the FCPA. Abbott also sent Alere’s head of finance in India on an unjustified “long leave” to make him unavailable for interviews by Abbott so that, in the head of finance’s words, “*the truth will not come out in front of Abbott leadership.*” Similarly, Alere delayed disclosing the need to recall INRatio and the related need to take a substantial earnings charge until many months after the need for such action had become obvious. Alere also failed to disclose that, months before being cut off from CMS eligibility, CMS unilaterally shut off Arriva’s access to the HIPAA Eligibility Tracking System (“HETS”), the CMS system used to determine Medicaid beneficiary eligibility, which inhibited the Company’s ability to make accurate reimbursement requests to CMS. Indeed, Abbott was forced to file a lawsuit in order to obtain access to documents necessary to properly conduct due diligence with respect to these very issues.

On December 7, 2016, Abbott filed suit to terminate its merger agreement (the “Merger Agreement”) with Alere (announced on February 1, 2016) explaining in a press release that the foregoing developments amount to a material negative change in Alere’s business:

These numerous negative developments are unprecedented and are not isolated incidents brought on by chance. We have attempted to secure details and information to assess these issues for months, and *Alere has blocked every attempt*. This damage to Alere’s business can only be the result of a systemic failure of internal controls . . . combined with [a] *lack of transparency* . . .

¶141 (emphasis added).¹ In fact, in its complaint, Abbott alleged that “Alere continually act[s] like a company with something to hide.” ¶143. Alere is fighting to preserve the Merger Agreement and the \$29 million in special one-time “change in control” payments the Company’s senior executives would receive if the Merger Agreement were consummated – a powerful incentive for misrepresenting the relevant material facts and working to ensure the merger goes through.

The overwhelming nature and depth of Alere’s internal control failures, coupled with the individual Defendants’ motive to conceal these, among other, deficiencies, support a strong inference of scienter. Defendants, however, have premised their dismissal arguments on reading each of Plaintiffs’ well-pled factual allegations “standing alone” – a theme they repeat no less than six times in their brief. In doing so, however, Defendants betray the weakness of their arguments by ignoring clear directives of the U.S. Supreme Court and the U.S. Court of Appeals for the First Circuit to look at the total mix of information rather than analyzing each allegation in isolation. Plaintiffs have pled actionable securities fraud claims against Defendants, and Defendants’ motion should be denied.

SUMMARY OF FACTS

Defendants

Alere provides diagnostic testing for diseases and toxicology and distributes its products through offices in 32 countries. ¶1. Defendant Namal Nawana (“Nawana”) became the Company’s Chief Executive Officer (“CEO”) on October 25, 2014 after being the Company’s

¹ References to “¶__” are to paragraphs of the Complaint.

interim CEO and, before that, its Chief Operating Officer. ¶¶17, 27. Defendant James F. Hinrichs (“Hinrichs”) has been, since April 6, 2015, Alere’s Chief Financial Officer (“CFO”). ¶18. Defendant Carla R. Flakne (“Flakne”) was Alere’s Chief Accounting Officer until March 31, 2016. ¶19.

Alere Assured Investors of the Adequacy of Internal Controls Despite Ample Internal Evidence That Those Representations Were False

A key driver of Alere’s growth has been acquiring smaller companies with different systems, reporting structures and practices for reporting revenues in various countries. ¶44. Nonetheless, Defendants Nawana and Hinrichs repeatedly assured investors that Alere had designed “disclosure controls and procedures” and “internal control over financial reporting” to ensure that “material information” relating to Alere, “including its consolidated subsidiaries,” was made known to Nawana and Hinrichs by such “consolidated subsidiaries.” ¶¶17, 18, 35, 210-12. Nawana and Hinrichs also certified that they had designed internal controls over financial reporting adequate to “provide reasonable assurance regarding the reliability of [Alere’s] financial reporting,” and claimed that each Alere quarterly and annual filing with the SEC “disclosed ... *all* significant deficiencies and material weaknesses in the design or operation of internal control over financial operation which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information.” ¶210.

The Company disclosed in 2015 material weaknesses in its internal controls relating to tax reporting arising from not maintaining sufficient resources and personnel with adequate experience and expertise in accounting for taxes. ¶¶34, 37-39. Defendants, however, contrary to their many public statements assuring investors of the adequacy of internal financial controls, failed to disclose that these same issues were causing a lack of adequate internal financial controls undermining Alere’s ability to accurately report its financial results. ¶¶32, 40-45, 96-98.

As a former Alere Senior Accountant in Western Europe from 2011 through 2014 (the “Senior Accountant”) stated, there was a lack of internal controls at Alere. He described Alere as consisting of approximately 200 entities, and he believed that the Company’s financial information system could not ensure it accurately compiled all of the necessary information in part because revenue was typically reconciled using simply an Excel file. ¶41. Likewise, a former Alere National Sales Manager in India from 2013 through early 2015 stated that Alere’s operations in India used a “not very effective reporting management system” to track and report sales, which was “very primitive.” ¶43.

Defendants Set Up Alere for Sale and a Multi-Million Dollar Payday for Nawana and Hinrichs

In October 2014, Nawana became CEO and President, and Alere implemented change in control benefits for Alere’s executives. ¶¶27-28. Those benefits would result in a \$20.5 million payment to Nawana and an \$8.7 million payment to Hinrichs in the event Alere was sold. ¶28. Alere subsequently sold off more of its operations in January 2015 as part of a continuing effort to make itself a more attractive acquisition candidate, and retained J.P. Morgan as its investment banker. ¶¶24, 29.

INRatio’s Recall Becomes Likely by the Fourth Quarter of 2015

INRatio was Alere’s hand-held blood coagulation monitoring system for use by patients and healthcare professionals in the management of medication to prevent blood clots. ¶47. Abbott has described INRatio as one of Alere’s “showcase” products. ¶59. However, the FDA received more than 9,000 reports of malfunctions with INRatio products and more than 1,400 reports of injuries. ¶¶46, 57. These amounts were far higher than with similar devices, such as the market leader Roche’s product, which had only 95 injury reports during the same period. ¶57.

According to a former Alere Global VP of Customer Service, Alere's standard protocol in responding to customer complaints about INRatio was to attribute it to "user error" (*i.e.*, the INRatio device itself was not defective), although "nobody internally believed that was the case." ¶48. A former Alere Quality Control Associate also stated that Alere needed to recall INRatio because "it didn't work." ¶49. She had heard complaints from customers that the device would "fluctuate a lot," giving a correct result in one test and a false result in the next. ¶49. Indeed, INRatio products had a higher number of "high-severity" complaints than any other Alere device, which were customer complaints that involved an adverse event. ¶51.

In October 2015, INRatio's technical issues worsened, with the Company needing to nearly double the quality assurance staff needed to field customer complaints. ¶51. Alere attempted, but failed, to implement software enhancements to INRatio to address the variability in its results. ¶54. As a result, Alere needed to take a substantial charge against earnings for a recall of INRatio, facts which Defendants did not disclose until many months later. *See* ¶58.

Alere Announces Abbott's Agreement to Buy Alere

On December 10, 2015, during Defendants' ongoing efforts to primp the Company for sale (*see* p. 6, *supra*), Abbott proposed to acquire the Company. ¶69. On December 14, 2015, at an Alere Board meeting, the Company's financial advisor J.P. Morgan discussed a list of potential strategic counterparties with Alere's Board that it had prepared before the Abbott contact. ¶70. In the following weeks, four entities expressed interest in a potential transaction with Alere. ¶71. On January 11, 2016, Alere gave a presentation at a J.P. Morgan healthcare conference that included a summary of the Company's financial information for the first 9 months of 2015 (including its purported income, which Alere only later disclosed was overstated by approximately 67%) and an image of the INRatio2 device. ¶72.

On February 1, 2016, Alere filed a Form 8-K with the SEC announcing that it had entered into the Merger Agreement with Abbott and representing that: (i) Alere's SEC filings did not contain any untrue statement or omission of material fact; (ii) the Company's financial statements had been prepared in accordance with SEC rules and GAAP; (iii) Alere maintained a system of adequate internal controls over financial reporting; and (iv) Alere was in compliance with all relevant state and federal laws, including the FCPA. ¶¶76-77. Abbott had agreed to pay \$56.00 for each share of Alere stock for a total acquisition price of \$5.8 billion, representing a highly lucrative premium to Alere's then-current trading price of \$37.20 per share. ¶¶2, 75.

Alere is Unable to Timely File Its 2015 Form 10-K Throwing its Merger With Abbott into a State of Uncertainty

On February 26, 2016 – just 25 days after Alere announced its merger with Abbott – the Company disclosed that it was unable to timely file its 2015 Form 10-K but expected to do so within the 15-day extension period. ¶78. On March 15, 2016, Alere acknowledged its inability to file its 2015 Form 10-K within the 15-day extension period because it was “continuing to conduct an analysis of certain aspects of the timing of revenue recognition, more specifically, revenue cutoff, in Africa and China for the years ended December 31, 2013, 2014 and 2015 (and each of the quarters in those annual periods).” ¶79. Alere further disclosed that on March 11, 2016, the Company had received a grand jury subpoena from the DOJ relating to, “among other things, sales, sales practices and dealings with third-parties (including distributors and foreign governmental officials) in Africa, Asia and Latin America and other matters related to the [FCPA],” sales practices which, according to an analyst, potentially made up 25% of Alere's revenues. ¶¶79, 80. In response to the Company's disclosures, the price of Alere's stock fell sharply, from \$53.46 on March 14, 2016 to \$49.32 per share on March 15, 2016. ¶81.

On April 20, 2016, Abbott's CEO Miles White refused to reaffirm Abbott's commitment to the merger which caused Alere's stock to drop by \$6.11 or 12% to \$43.36 per share. ¶85. On April 28, 2016, Alere disclosed that Abbott was expressing "serious concerns" about the "accuracy of various representations, warranties and covenants made by Alere in the parties' merger agreement," relating to, among other things, Alere's delay in filing its 2015 Form 10-K and the pending governmental investigations. ¶86. Alere also disclosed that Abbott had offered Alere \$30-\$50 million to void the Merger Agreement, further causing the price of Alere stock to fall by 10%, to close at \$39.00 per share. ¶¶86, 89.

Alere Recalls INRatio and Then Discloses Knowing of Those Facts in 2015

On July 11, 2016, Alere announced the recall of INRatio products because in certain cases the blood-monitoring systems provided blood clotting time "that is clinically significantly lower than" tests done at laboratories. ¶93. On July 12, 2016, the Company disclosed that, in connection with the INRatio recall, Alere expected to record approximately \$70-\$90 million of related charges in 2016 and an immediate non-cash impairment of \$20-23 million and accelerated depreciation of approximately \$33-37 million. ¶94. On August 8, 2016, the Company disclosed that it had already taken a \$43 million charge in the fourth quarter of 2015 with respect to the need to recall INRatio. ¶116.

Alere Files its 2015 10-K and Discloses That Internal Control Weaknesses Have Still Not Been Effectively Resolved

On August 8, 2016, more than five months after its original due date, Alere finally filed its 2015 Form 10-K, disclosing disappointing results that were below Alere's prior estimates and analysts' consensus, and the need to restate previously reported interim quarterly results. ¶¶104-105. Alere also made material changes to its reported income (loss) from continuing operations and decreases in previously-reported income from continuing operations of **67%** for the nine

months ending September 30, 2015, which Alere acknowledged were material. ¶¶ 97,105. In addition, those revisions demonstrated that: the Company had not, as previously represented, met analysts' expectations for net revenue for second quarter 2015 (¶106); Alere's previously reported income for the third quarter of 2015 from continuing operations transformed to a loss (¶105); and Alere's revenue of \$623 million for the fourth quarter of 2015 was below consensus estimates of \$627.8 million, and decreased 6.6% from the fourth quarter of 2014. ¶104.

Defendants also were forced to acknowledge continued material weakness in Alere's internal controls over financial reporting impairing Alere's ability to report accurate financial information. ¶¶107-09.² Indeed, the Company admitted that its unaudited financial statements and results, even as of this date, may not be relied upon, as the Company is unable to ensure that its financial statements do not include material misstatements. ¶112.

Alere's Operating Units Face Dire Regulatory Scrutiny

Alere continued to disclose throughout 2016 and early 2017 material negative developments in its subsidiaries that resulted from flawed internal controls and communications structures at the Company. Thus, on March 15, 2016, Alere disclosed that the Company had received a grand jury subpoena from the DOJ "requiring the production of documents relating to, among other things, sales, sales practices and dealings with third-parties (including distributors and foreign governmental officials) in Africa, Asia and Latin America and other matters related to the U.S. Foreign Corrupt Practices Act." ¶65.

² The material weaknesses arose from failures to: (i) maintain a sufficient complement of resources at Alere's subsidiaries with appropriate knowledge, experience and training to ensure proper application of GAAP in determining revenue recognition; (ii) maintain effective controls over information and communications as it relates to revenue recognition at Alere's subsidiaries; (iii) design effective controls over the review of terms of purchase orders and customer contracts, including amendments to contracts, to ensure proper application of GAAP in determining revenue recognition; and (iv) design effective controls to ensure that revenue would not be recognized until title and risk of loss had passed to our customers. ¶109.

According to a former Alere National Sales Manager in India from 2013 through early 2015, an outside audit firm had conducted an investigation into Alere's government bidding practices in India that began in approximately late summer and early fall of 2013. ¶66. The former National Sales Manager stated that the government bidding process was "highly corrupted," that Alere was able to secure business in India through "under the table" dealings, that Alere's policies for ensuring adherence to anti-corruption laws were not open or transparent, and that most of Alere's practices in India did not match global policies. ¶¶66-67.

On July 27, 2016, Alere disclosed that it had received a subpoena from the DOJ Criminal Fraud Unit seeking information about the Company's toxicology unit and its efforts to collect co-payments from patients. ¶60. The DOJ was also investigating whether Alere made payments to doctors who ordered tests from Alere that constituted illegal kickbacks. *Id.* Alere's unit, which was the subject of the probe, accounted for one quarter of the Company's \$2.57 billion revenue in 2014. *Id.* In response to the Company's disclosure of this investigation, Alere shares fell 29%, falling from a closing price of \$44.06 per share on July 26, 2016 to close at \$31.47 per share on July 27, 2016, on high trading volume. ¶103.

Alere has been on notice of improprieties in its toxicology unit since at least August 2013, when Horizon Blue Cross and Blue Shield filed a complaint against Alere and Alere Toxicology alleging that they committed insurance fraud by making false and fraudulent insurance claims for unnecessary tests. ¶61. A former Alere Toxicology Billing and Pricing Supervisor stated that while she worked in Alere's Florida office in 2014, two Medicare audits and one internal audit were happening at the same time and based upon these audits, Alere learned that problems existed with its billing practices. ¶64. The former supervisor assisted with

pulling documents for the Medicare audit and found that the documentation did not support the medical necessity for the testing Alere had performed. *Id.*

On November 4, 2016, Alere disclosed that CMS was revoking the Medicare enrollment of Alere's subsidiary, Arriva, which furnishes diabetic testing supplies via mail order because over a five-year period Arriva had submitted claims to Medicare for 211 deceased patients.

¶133. Prior to CMS's October 2016 revocation of Arriva's Medicare enrollment, Arriva had a long, recidivist history of violating Medicare provisions and was the subject of numerous investigations concerning such misconduct. ¶¶135-36. For example, Arriva's predecessor settled claims that it submitted false claims to Medicare for \$18 million in April 2012, and, in Alere's 2014 Form 10-K, dated March 5, 2015, Alere disclosed that Arriva was in the process of responding to a CID from the U.S. Attorney for the Middle District of Tennessee in connection with an investigation of possible improper claims submitted to Medicare and Medicaid, and that investigation was still pending as of November 4, 2016. ¶¶137-38.

Abbott and Alere Litigate Over the Merger

On August 25, 2016, Alere sued Abbott to force Abbott to complete the application process for various antitrust approvals in connection with the Merger Agreement. ¶124. Abbott characterized Alere's lawsuit as a publicity stunt. Abbott attributed any purported delay in Abbott's ability to submit information to antitrust authorities to Alere's inability to "get its act together" and report accurate financial information. Abbott attributed such failure to Alere's severe material weaknesses in its internal controls. ¶126. Abbott also filed with the Delaware court a previously-undisclosed e-mail from Alere India's Director of Finance, stating that Alere was interfering with Abbott's attempts to investigate possible legal violations by Alere by coaching witnesses to provide false information, retaliating against those who refused, and even sending Alere's head of finance in India on an unjustified "long leave" to make him unavailable

for interviews. ¶127. In opposing Alere’s motion for expedited proceedings in that lawsuit, Abbott stated that “[f]or months, Alere refused Abbott’s request to review critical financial information and transaction data, and failed to provide updates regarding the magnitude of the impact of its years of accounting errors.” ¶241. Abbott additionally stated “Alere has refused, even to this day, to hand over the documents and data Abbott needs to understand Alere’s accounting errors and internal control problems.” *Id.*

On November 3, 2016, Abbott then filed suit against Alere for its refusal to provide Abbott with access to Alere’s financial and business information. The information withheld by Alere included accounting records and other documents needed to assess Alere’s compliance with the FCPA; Medicare and Medicaid claims detail required to evaluate Alere’s compliance with government health care laws; and information regarding Alere’s payments to physicians necessary to understand Alere’s compliance with the Anti-Kickback Statute and Stark Law.

¶131. On November 15, 2016, Abbott and Alere agreed to settle the breach of contract action by having Alere turn over to Abbott “files about bribery probes of [Alere’s] foreign operations and U.S. billing practices.” ¶132. However, as Abbott later stated, Alere has still not provided those documents. *Id.*

On December 7, 2016, Abbott sued Alere to terminate the Merger Agreement because Alere’s announcement of “an endless sequence of serious problems” made the Company “a materially different company from the one Abbott agreed to buy.” ¶¶8, 142. Alere, according to Abbott, had already been “stripped of substantial businesses, product lines, and revenue streams,” and “[a]ny one of these striking developments would be troubling but together they reveal a much deeper problem: a fundamental lack of controls throughout the company coupled with minimal transparency about these events.” ¶8. Specifically, Abbott has stated that Alere

suffers from a “fundamental lack of controls throughout the company” that adversely affect Alere’s business operations and which “were never before disclosed to . . . the public.” ¶¶142-43. Two weeks later, Abbott’s efforts to obtain visibility into the nature and scope of Alere’s internal control deficiencies has been met “with obfuscation and concealment” by Alere, which has given Abbott the impression that “Alere continually act[s] like a company with something to hide.” ¶143.

Alere is Unable to Timely File Its 2016 Form 10-K and Is Forced to Disclose New Revenue Errors From 2015

On March 1, 2017, Alere announced that it was unable to timely file its 2016 Form 10-K (but hoped to do so within the 15-day extension period) because of continued material weaknesses in its internal controls over financial reporting, including because of “inappropriate conduct” at the Company’s subsidiary in South Korea. *See* Abraham Decl. Ex. A. Following the same script as the year before, Alere disclosed, two weeks later that it would be unable to file its 2016 Form 10-K within the extension period and stated that it had not yet determined whether the correction of the misstatements in its 2015 financial results of \$5-10 million of revenue improperly recorded at the Company’s South Korean and Japanese subsidiaries would require the Company to issue a restatement. *See* Abraham Decl. Ex. B. (March 15, 2017 8-K). Also, on March 1, 2017, *Bloomberg* reported that Alere’s latest disclosure “tests the limits of patience” because the Company “can’t seem to go very long without divulging more bad news.” Abraham Decl. Ex. C.

ARGUMENT

I. PLAINTIFFS HAVE ALLEGED FACTS GIVING RISE TO A STRONG INFERENCE THAT DEFENDANTS ACTED WITH SCIENTER

Scienter exists where “defendants either ‘consciously intended to defraud, or that they acted with a high degree of recklessness.’” *Miss. Pub. Employees’ Ret. Sys. v. Bos. Sci. Corp.*,

523 F.3d 75, 85 (1st Cir. 2008) (quoting *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 82 (1st Cir. 2002)). A strong inference of scienter can be supported by indirect or circumstantial evidence because the inference of scienter “need not be irrefutable” or “of the ‘smoking-gun’ genre.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). *See also Aldridge*, 284 F.3d at 82 (1st Cir. 2002) (“Inferences must be reasonable and strong – but not irrefutable . . .”). Instead, the inference of scienter need only be “at least as compelling as any [plausible] opposing inference one could draw from the facts alleged.” *Id.*; *see also Sloman v. Presstek, Inc.*, 2007 U.S. Dist. LEXIS 69475, at *25 (D.N.H. Sept. 18, 2007) (“a tie [] goes to the plaintiff.”).

A. The Total Mix of Information Supports a Strong Inference of Scienter

Defendants premise their motion to dismiss on Plaintiffs’ purported need to separately allege a strong inference of scienter with respect to each separate fact. Indeed, on no less than six occasions, Defendants attack Plaintiffs’ scienter allegations as being insufficient “standing alone.”³ However, Defendants’ premise is inherently flawed as it is well-settled that the relevant test is whether “*all* of the facts alleged, taken collectively . . . not whether any individual allegations, scrutinized in isolation, meets that standard.” *Tellabs*, 554 U.S. at 322-23 (emphasis

³ Defendants’ repeated attempts to view the Complaint’s scienter allegations in isolation (in the face of the clear principle that a scienter analysis must take the allegations collectively) demonstrates the weakness of their argument that their materially false and misleading statements were not made with scienter. *See* Memorandum of Law in Support of Defendants’ Motion to Dismiss the Supplemental and Amended Consolidated Class Action Complaint (“D.B.”) (ECF No. 81) at 12, 29 (quoting *Smith v. First Marblehead Corp.*, 55 F. Supp. 3d 223, 231 (D. Mass. 2014)) (“GAAP violations or accounting irregularities, ***standing alone***, are insufficient to state a securities fraud claim”) (emphasis added); D.B. at 13, n.49 (quoting *In re Cirrus Logic Sec. Litig.*, 946 F. Supp. 1446, 1458 (N.D. Cal. 1996) (“[T]here can be no claim of fraud ***based merely*** on a company’s deviation from its own undisclosed internal accounting policies.”) (emphasis added); D.B. at 19, n.75 (citing *In re Vertex Sec. Litig.*, 357 F. Supp. 2d 343, 352-53 (D. Mass. 2005)) (“a significant financial incentive, such as an upcoming merger, ***is insufficient alone*** to satisfy the scienter requirement”); D.B. at 20 (quoting *Karpov*, 2010 U.S. Dist. LEXIS 59771, at *31) (“allegations of material weaknesses in internal controls ‘do not, ***standing alone***, give rise to a strong inference of scienter . . .”) (emphasis added); D.B. at 33, n.116 (quoting *Avid*, 28 F. Supp. 3d at 114) (stating that a government investigation “***is insufficient in and of itself***” to support an inference of scienter) (emphasis added).

in original); *see also In re Cabletron Sys. Inc.*, 311 F.3d 11, 40 (1st Cir. 2002) (“[e]ach individual fact about scienter may provide only a brushstroke, but the resulting portrait satisfies the requirement for a strong inference of scienter under the PSLRA”) (citations omitted).

Here, Defendants’ different type of misconduct “fit together and reinforce one another [which] strongly suggests a conscious course of conduct.” *Washtenaw Cty. Emps. Ret. Sys. v. Avid Tech., Inc.*, 28 F. Supp. 2d 93, 114 (D. Mass. 2014) (quoting *Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 16 (D. Mass. 2004)) (the presence of fraudulent contract accounting and failure to maintain adequate internal controls fit together). For example, Alere’s failure to maintain adequate internal controls led to the Company’s incorrect reporting of financial results. *See id.* Similarly, the failure to maintain adequate financial controls enabled violation of the FCPA which is intimately tied to maintaining proper records sufficient to uncover instances of foreign bribery. *See* 15 U.S.C. §78m(b) (2017); *In re Immucor Inc. Sec. Litig.*, 2006 U.S. Dist. LEXIS 72335, at *36-37 (N.D. Ga. Oct. 4, 2006). The absence of internal financial internal controls fits together with the Company’s failure to maintain proper billing procedures in Arriva and Alere’s toxicology unit. Indeed, that is the way that Abbott, which planned to be the biggest purchaser of Alere’s stock through the Merger Agreement, sees the facts as it has unequivocally stated that: “[t]hese numerous negative developments are unprecedented and ***are not isolated incidents brought on by chance.***” ¶141 (emphasis added). *See also Frank v. Dana Corp.*, 646 F.3d 954, 961-62 (6th Cir. 2011) (allegations viewed holistically relating to inadequate internal controls and misreporting of financial results while the company was attempting to obtain financing support a strong inference of scienter).

B. The Individual Defendants' Motive to Personally Profit from Alere's Sale Supports a Strong Inference of Scienter

Although the “absence of a motive allegation is not fatal” to alleging a strong inference of scienter, a motive to commit fraud, when combined with other facts, supports a strong inference of scienter. *Tellabs*, 551 U.S. at 325 (“[P]ersonal financial gain may weigh heavily in favor of a scienter inference[.]”); *see also Cabletron*, 311 F.3d at 39 (citing *Aldridge*, 284 F.3d at 82 (1st Cir. 2002)). Here, Defendants Nawana and Hindrichs stood to gain \$29 million in bonus payments from the successful sale of the Company to Abbott which, in part, resulted from change of control benefits implemented in October 2014, *i.e.*, *after* Alere had already received one takeover proposal. ¶28. Defendants were, therefore, highly motivated to secure a sale of Alere before adverse information about the Company was disclosed to the market. *See Collier v. ModusLink Glob. Sols., Inc.*, 9 F. Supp. 3d 61, 75 (D. Mass. 2014) (motive and opportunity pled where officers, by perpetuating the fraud, benefitted by appearing as effective managers and thus stood to earn additional financial incentives); *Chalverus v. Pegasystems, Inc.*, 59 F. Supp. 2d 226, 236 (D. Mass. 1999) (motive and opportunity pled where officers’ compensation packages were correlated to company’s stock price); *see also In re Enron Corp. Sec. Derivative & ERISA Litig.*, 235 F. Supp. 2d 549, 686 (S.D. Tex. 2002) (“[I]ining one’s pockets with gold, at the expense of investors, employees and the public, appears too often to be a dominating ambition[.]”).

Defendants attempt to negate the inference of scienter by contending that Abbott’s offer to acquire Alere was “unsolicited.” D.B. at 37.⁴ However, even assuming *arguendo* that the

⁴ Defendants’ describing Abbott’s offer as unsolicited (D.B. at 38) is also infirm as it relies on Alere’s recitation of the factual background of the merger in a proxy disseminated *after* this lawsuit was commenced. However, even the proxy does *not* state that the offer was “unsolicited” but, instead, only that Abbott contacted Alere on December 10, 2015. *See* Declaration of Richard A. Rosen in Support of Defendants’ Motion to Dismiss the Supplemental and Amended Consolidated Class Action Complaint,

offer made by Abbott in December 2015 was “unsolicited,” Defendants were actively seeking to sell Alere prior to that time and would have learned that numerous persons and entities were interested in acquiring the Company, including Alere’s former CEO and Abbott. ¶¶ 21-31. Defendants’ awareness of those facts that motivated them to withhold the material negative information about the Company from the market, in order to induce suitors such as Abbott to make their offer for the Company. Abbott’s offer to purchase Alere was the logical (and desired) outcome of the process that Defendants set in motion as early as mid-2014, and for which the Company had engaged outside investment banking firm JP Morgan before Abbott made its offer. *See id.* Indeed, Defendants’ tenacious attempts to forge through the Merger even though Abbott publicly expressed a desire to discontinue supports the significant motivating power of the deal and its importance to Defendants. ¶¶ 124-27.

Equally lacking in merit is Defendants’ contention that any inference of scienter is negated by increases in and failure to sell stock holdings by the Individual Defendants. Nawana and Hinrichs ***were attempting to sell their shares*** during the Class Period by trying to sell Alere. Therefore, Nawana’s not selling as well as any purchases of shares made by Defendant Hinrichs are consistent with their desire and expectation that they would ultimately profit from their deception when the Company was sold (for a price above any price that Alere stock was trading at during the Class Period). *See, e.g., N.J. Carpenters’ Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 55 (1st Cir. 2008) (“If there is reason to be concerned about material

Ex. 17-15 (ECF No. 82-17). Even if Defendants accurately described the proxy’s contents, it would not matter because a court’s taking judicial notice of the contents of an SEC filing does not establish the truth of the statements it contains. *See, e.g., Garber v. Legg Mason Inc.*, 347 Fed. App’x. 665, 669 (2d Cir. 2009); *LoConte v. Forest Labs., Inc., (Celexa & Lexapro Mktg. & Sales Practices Litig.)*, 2015 U.S. Dist. LEXIS 77698 at *12-13 (D. Mass. June 15, 2015).

omissions or misrepresentations, the presence of insider trading can be used, in combination with the other evidence, to establish scienter.”) (citations omitted).⁵

C. Defendants’ Efforts to Hide Key Facts Also Supports a Strong Inference of Scienter

The facts presented by Abbott in the Merger Agreement litigation also bolster the strong inference of scienter because, among other things, they establish that Alere willfully concealed material facts from Abbott in an effort to force through the Merger on its original terms. Instead, Abbott was forced to initiate legal action in order to obtain documents directly relating to Defendants’ knowledge of, among other things, inadequate internal controls over the Company’s financial statements and payments of foreign bribes. *See, e.g.*, ¶131. Defendants’ effort to conceal adverse facts from Abbott further demonstrates Defendants’ knowing or reckless disregard of facts that undermined their statements to investors. *See, e.g., Cabletron*, 311 F.3d at 39 (recognizing motive when defendants “conceal[ed] . . . the serious and worsening deterioration of [the company’s] financial health”); *SEC v. Collins & Aikman Corp.*, 524 F. Supp. 2d 477, 492-93 (S.D.N.Y. 2007) (defendant’s effort to conceal facts via false documents and false statements create an inference that the defendant acted to defraud investors).

Defendants’ argument that this Court should not rely upon Abbott’s allegations against Alere lacks merit. Abbott’s allegations are clearly well-grounded in fact based upon, among other things, their referencing an email from Alere’s India Director of Financial to support its claims that Alere is withholding material adverse information. ¶127. In addition, Alere agreed to settle the suit that Abbott filed against it for withholding information by agreeing to produce that information (¶132) – a tacit admission Alere had withheld the information in the first place.

⁵ *In re Bristol-Meyers Squibb Sec. Litig.*, 312 F. Supp. 2d 549 (S.D.N.Y. 2004), upon which Defendants rely, did not involve a case, such as the one at bar, in which the motive allegations are premised on a successful sale of the Company at a premium price.

Finally, in recent court proceedings in Delaware Chancery Court, Alere admitted that it had not yet provided Abbott with certain due diligence documents. *See* Abraham Decl. Ex. E at 25-26.

Moreover, this Court may take judicial notice pursuant to Fed. R. Evid. 201(b) of Abbott's factual contentions made under the requirements of Rule 11.⁶ *See, e.g., Washtenaw Cty. Emps.' Ret. Sys. v. Talbots, Inc.*, 2013 U.S. Dist. LEXIS 135692, at *55-56 (D. Mass. July 3, 2013) (“[M]atters of public record are fair game in adjudicating Rule 12(b)(6) motions, and a court's reference to such matters does not convert a motion to dismiss into a motion for summary judgment.”) (quoting *In re Colonial Mortg. Bankers Corp.*, 324 F.3d 12, 19 (1st Cir. 2003)); *AES P.R., L.P. v. Trujillo-Panisse*, 133 F. Supp. 3d 409, 415, (D.P.R. 2015) (“documents on file in federal or state courts are proper subjects of judicial notice”) (citations omitted). Indeed, the Supreme Court has specifically directed courts in deciding whether a strong inference of scienter has been properly alleged to take into account “matters of which a court may take judicial notice.” *Tellabs*, 551 U.S. at 322.

Aronson v. Advanced Cell Tech., Inc., 972 F. Supp. 2d 123 (D. Mass. 2013), upon which Defendants rely, is inapposite here because the pleading incorporated by reference purported to summarize facts contained in other documents which the plaintiff did eventually rely upon to sustain his claims. Here, in contrast, Abbott's allegations represent a direct contention of a litigant concerning facts based upon its personal knowledge and what happened to Abbott. Defendants' argument that this Court should ignore those statements not only conflicts with *Tellabs* but is also illogical because Abbott's statements do not suffer in comparison with those of a confidential witness which may be considered in deciding whether a claimant has properly alleged a strong inference of scienter.

⁶Rule 11 of the Delaware Court of Chancery is the same as Fed. R. Civ. P. 11.

Equally meritless is Defendants' assertion that their "voluntary" disclosure of the accounting misstatements negated a strong inference of scienter. D.B. at 18-19. That disclosure was made in a Form 10-K requiring audited financial statements and sign-off by the Company's auditor, PricewaterhouseCoopers, and a mandatory disclosure is not "voluntary." *See, e.g., United States ex rel. Griffith v. Conn*, 2015 U.S. Dist. LEXIS 22668, at *31-32 (E.D. Ky. Feb. 24, 2015) (a disclosure required by law is not voluntary). As a result, Defendants' factual contention is highly questionable because it is at least as likely, if not more likely, that the disclosure was precipitated by Alere's auditors.

In addition, even assuming *arguendo* that the disclosure was "voluntary," it only came *after* Alere had made successful use of its prior misrepresentations in order to facilitate the Company's entering into the Merger Agreement with Abbott. By that time, especially given Abbott's demands for information during the due diligence process, it was likely a foregone conclusion that Abbott would soon learn the truth about Alere's deficient internal controls.

Defendants' assertion of voluntary disclosure is further undermined by Alere withholding material information from Abbott (and the public) during the course of the due diligence process (¶¶99, 119, 126-27, 131-32, 141, 143), including preventing Abbott from interviewing the Alere India Director of Finance. ¶127. Moreover, even Alere's belatedly-filed 2015 Form 10-K failed to disclose all of the material facts concerning Alere's need to restate earnings. Instead, under litigation pressure from Abbott, after initially failing to voluntarily produce key documents, Alere has very recently disclosed yet another error in revenue recognition and its inability to file its 2016 Form 10-K with the SEC on time. *See* Abraham Decl. Ex. A and B.⁷

⁷ *Messner v. USA Techs., Inc.*, 2016 U.S. Dist. LEXIS 50132 (E.D. Pa. Apr. 13, 2016), upon which Defendants rely, is a useful contrast with the facts of this case. In *Messner*, the late filing notice stated that "management identified deficiencies" in the company's financial reporting and, a day later, the company filed corrected financial statements. *Id.* at *9-10. Here, the need to correct Alere's financial

D. The Materiality of Defendants' Misrepresentations Supports a Strong Inference of Scienter

“The question of whether a plaintiff has pled facts supporting a strong inference of scienter has an obvious connection to the question of the extent to which the omitted information is material.” *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 757 (1st Cir. 2011). The magnitude of falsity is recognized as a factor supporting a strong inference of scienter. *See, e.g., Anderson v. Spirit AeroSystems Holdings, Inc.*, 827 F.3d 1229, 1255 (10th Cir. 2016). This well-settled principle applies with equal force to those situations involving false statements about internal financial controls. *See, e.g., Avid*, 28 F. Supp. 3d at 114 (holding that one of the contributing factors to the strong inference of scienter, taken together with the magnitude of the restatement, included plaintiffs’ detailed description of “the many instances where the [c]ompany acknowledged internal control deficiencies”); *Crowell*, 343 F. Supp. 2d at 20 (“egregious” internal controls supported strong inference of scienter).

Defendants do not, nor could they reasonably, contend that Alere’s weaknesses in internal controls over financial reporting were immaterial.⁸ The magnitude of Alere’s internal financial control failures was enormous: a host of internal control weaknesses, including those related to internal revenue recognition and an insufficient complement of resources at Alere’s subsidiaries; and no less than four additional material weaknesses *to which Alere admitted* in its

statements took more than five months. ¶¶5, 104. In addition, since that time, even that restatement has been found wanting with the disclosure of the need for additional adjustments or a restatement. *See Abraham Decl. Ex. A.*

⁸ Materiality is a mixed question of law and fact that courts find inappropriate for resolution at the motion to dismiss stage. *See Ganino*, 228 F.3d at 162 (dismissal on materiality grounds is only appropriate where reasonable minds could not differ on the question of their importance to a reasonable investor). Defendants ignore that the alleged omitted material facts do not relate solely to the amount of the restatement but to Defendants’ failure to disclose a host of other material adverse facts. ¶¶224-25. For Defendants’ motion to dismiss to be successful, the Court would have to hold that all of those withheld facts, taken individually and collectively, are not material, which is not the case.

2015 Form 10-K. ¶¶7, 32-45, 107, 229. Indeed, Alere needed to delay the filing of its Form 10-K by more than five months (¶¶5, 104) and, even to this day, more than one year later, Alere continues to caution investors that the *internal control weaknesses “have not been remediated, and these or other material weaknesses could impair our ability to report accurate financial information in a timely manner. . . .”* ¶108 (emphasis added); *see also* Abraham Decl. Ex. B.

Moreover, these weaknesses are the subject of specific public representations made by Defendants in connection with the Merger Agreement and in certifications signed by Defendants Nawana and Hinrichs throughout the Class Period publicly affirming the adequacy of the Company’s internal financial controls. ¶¶17-18, 210-212. The belated revelation of those weaknesses are also connected to the first drops in the price of Alere’s stock on March 15, 2016 (¶81) and Abbott’s initial recalcitrance to proceed with the Merger Agreement which precipitated two additional material declines in the price of the Company’s stock (¶¶82-89).

Defendants’ assertion that the Company’s improper revenue recognition was immaterial because of the relatively minor impact on net revenue and gross margins (D.B. at 21) is fundamentally inconsistent with the Company’s own July 14, 2016 press release stating that it expected the cumulative effect of the misstatements would be material to the year ended December 31, 2015. ¶97. In addition, that argument ignores that Alere’s restatement arose out of GAAP violations which are deemed material because “[a]ccurate earnings figures are vital aspects of the ‘total mix of information’ which investors would consult when evaluating [a company’s] stock.” *In re Cabletron Sys., Inc.*, 311 F.3d 11, 35 (1st Cir. 2002).

However, even had Alere not admitted to the materiality of its restatement and the failure to accurately report the Company’s financial results had not involved a GAAP violation – and it did – Defendants’ formulaic approach of relying on a single numerical benchmark or quantitative

amount to determine materiality is inherently flawed and contrary to the law. Instead, the relevant assessment also includes qualitative factors such as whether the misstatement masked a change in earnings or other trends or whether the misstatement hid a failure to meet analysts' consensus expectations at issue. *See, e.g., Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 163 (2d Cir. 2000) (quoting SEC Staff Accounting Bulletin ("SAB") No. 99, 64 Fed. Reg. 45,150, 45,152 (1999) (codified at 17 C.F.R. pt. 211, subpt. B) (finding SAB No. 99 persuasive guidance for evaluating the materiality of an alleged misrepresentation as SAB No. 99 enumerates qualitative factors such that even quantitatively small amounts can be material)).

Crowell is on point with the facts of this case, as it involved revenues being restated by less than 0.01% and expenses by only 0.3%. In *Crowell*, Judge Young rejected arguments identical in form to those made by Defendants characterizing them as "entirely specious" and, instead, held that:

What matters most to investors is income, not revenues, and the restatement led to a downward revision of income for the first two quarters of that year from a total of \$ 4,000,000 to a total of \$ 2,700,000. This constitutes a 32.5 percent downward revision, hardly "minuscule."

343 F. Supp. 2d at 18 (citation omitted); *see also Van Noppen v. InnerWorkings, Inc.*, 136 F. Supp. 3d 922, 951 (N.D. Ill. 2015) (complaint sustained based upon a restatement of only \$2.2 million for issuer with annual revenues of approximately \$800 million).

Here too, the revision of Alere's financial statements for the nine months of 2015 ending September 30, 2015 had a dramatic impact on the Company, causing a reduction in its reported income from continuing operations of 67%. ¶105. In addition, the reported income from continuing operations for the third quarter of 2015 was decreased by 143%, to a loss. *Id.* Similarly, the Company revised its reported income in the second quarter of 2015, reducing it by more than one-quarter and causing the previously reported net revenue for the second quarter of

2015 (which had previously exceeded analysts' expectations) to, instead, fail to meet those expectations. ¶¶105-106. These facts provide more than an adequate basis for a jury or trier of fact to find Alere's GAAP violations material, especially given that Alere has recently announced yet another needed restatement of 2015 results. *See, e.g., Blatt v. Muse Techs., Inc.*, 2002 U.S. Dist. LEXIS 18466, at *22-23, 33 (D. Mass. Aug. 27, 2002).

Equally meritless is Defendants' effort to focus on revenues in arguing that the recall of INRatio products "was immaterial to Alere's overall financial performance because less than 2% of Alere's net revenue in 2015 was generated from the INRatio products and the charge (most of which was for non-cash items) that Alere took in 2015 in connection with the recall was only \$38 million." D.B. at 29. The INRatio recall, however, had a material effect on Alere's profits causing gross profits to decrease by \$99.7 million, or 8%, for 2015, from \$1.21 billion for 2014. Abraham Decl. Ex. D. In addition, Abbott has characterized INRatio as a material part of Alere's business which motivated its desire to acquire the Company. *See* ¶¶8, 119, 142.

In re Segue Software, Inc., Sec. Litig., 106 F. Supp. 2d 161 (D. Mass. 2000), upon which Defendants rely, is unavailing because that decision turned primarily on the plaintiffs' failure to allege a plausible motive, which is present in this case. *Id.* at 171. In addition, cutting against materiality in *Segue Software* was that the company's stock price appeared disconnected from earnings reports (*id.*) and in reaction to the restatement, the price of the company's per share stock price actually "rose from \$5.50 to \$6.313." *Id.* at 165. Here, Alere's stock price drop in reaction to Alere's failure to timely file the Company's 2015 Form 10-K, as well as Abbott's public recalcitrance at proceeding with the Merger Agreement. ¶¶81, 85, 89.⁹ In addition, *Segue Software* was decided more than one month before *Ganino* and it fails to cite or discuss SAB No.

⁹ The decline in Alere's common stock price upon each of the corrective disclosures at issue here further demonstrates the materiality of the undisclosed information. *See, e.g., Ganino*, 228 F.3d at 166-67.

99, making it inconsistent with those authorities and a correct interpretation of controlling principles of law.¹⁰ See, e.g., *In re PerkinElmer, Inc. Sec. Litig.*, 286 F. Supp. 2d 46, 54 (D. Mass. 2003) (citing *Ganino*, 228 F.3d at 162-63).

E. The Simple and Obvious Nature of Alere's GAAP Violations Supports a Strong Inference of Scienter

During the Class Period, Alere presented financial statements to investors that were inaccurate, unreliable, and did not comply with GAAP. An application of GAAP “that strays beyond the boundaries of reasonableness will provide evidence from which scienter can be inferred.” *In re Raytheon Sec. Litig.*, 157 F. Supp. 2d 131, 147 (D. Mass. 2001) (Saris, J). One such circumstance is when clear standards with respect to revenue recognition have been violated. See e.g., *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 203 (1st Cir. 1999) (violating GAAP standards such as FAS No. 48, relating to the timing of revenue recognition, “could provide evidence of scienter.”).¹¹

Here, Defendants’ misreporting of Alere’s financial results violated the basic and well-settled rule that in order for a company to properly recognize revenue both “ownership and its attendant risks” need to be transferred to the purchaser with consignment sales not qualifying for

¹⁰ *Glassman v. Computervision Corp.*, 90 F.3d 617 (1st Cir. 1996), upon which Defendants also rely, did not involve a required restatement of previously reported GAAP earnings (or any restatement whatsoever) and, like *Segue Software*, was decided before *Ganino*. *Id.* at 633. Defendants’ additional authorities are unavailing. For example, *ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187 (2d Cir. 2009) and *U.S. v. Nacchio*, 519 F.3d 1140 (10th Cir. 2008), cited by Defendants in a footnote, acknowledged the persuasive effect of SAB No. 99 relied upon in *Ganino*. *ECA* involved a case in which the qualitative factors were insufficient to cause the misstatements at issue to be material. Moreover, Defendants cite the discussion in *Nacchio* regarding the SEC’s 5% threshold for a restatement of revenues to be deemed material. D.B. at 22, n.82. Defendants fail to acknowledge that a restatement smaller than 5% was deemed material in that case and also fail to cite the later portion of the decision that states, quoting the SEC, that this threshold is only an “initial step” and the “magnitude of a misstatement is only the beginning of an analysis of materiality; it cannot appropriately be used as a substitute for a full analysis of all relevant considerations.” *Nacchio*, 519 F.3d at 1162-64 (quoting SAB No. 99, 64 Fed. Reg. at 45,151).

¹¹ In *Greebel*, the allegations were not sufficiently particularized to demonstrate that the defendants had, in fact, violated GAAP. *Id.* at 205.

revenue recognition under GAAP until sales are made to the end user. *See, e.g., Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 709 (7th Cir. 2008); *Malone v. Microdyne Corp.*, 26 F.3d 471, 478 n.8 (4th Cir. 1994) (it is inappropriate under GAAP to recognize revenue “in which the buyer has an unconditional right of return.”).¹²

Defendants attempt to create confusion where, in reality, simplicity reigns, by arguing that revenue is typically recognized when the relevant products are shipped. D.B. at 13 (citing SAB No. 104). However, that argument is only true because the time of shipment typically causes title and the risk of loss to pass to the purchaser. *See* ¶152 (GAAP, ASC 605-15-25-1); ¶153 (SAB No. 104). Indeed, Alere’s public disclosures accompanying their false financial statements exhibit no such confusion by, instead, clearly stating that: “[w]e **recognize revenue upon transfer of the title and risk of loss of the products to third-party customers . . .**” ¶156.¹³

That the improper revenue recognition took place overseas does not absolve Defendants from having been, at a minimum, reckless in issuing their false statements. Indeed, Defendants certified the adequacy of Alere’s internal controls with respect to the entire Company – not just Alere’s U.S. operations. ¶¶210-212. That Alere has a large international operation only heightened the critical importance of Defendants’ making certain that Alere had adequate

¹² The GAAP provision at issue in *Malone* was Financial Accounting Standard (FAS) No. 48 relating to the recognition of revenue. Accounting Standards Codification (ASC) 605 (AC¶¶150-52) have replaced, in relevant part, FAS No. 48. *See* Arun Misra, *The Universal Appeal of the US GAAP Codification*, Financial Executives International, http://www1.financialexecutives.org/eweb/upload/fei/ferf_acad_ArunMisra.pdf (last visited March 22, 2017). However, the same core principle that revenue only be recognized when title has passed remains the same. *See, e.g., SEC v. Escala Grp., Inc.*, 2009 U.S. Dist. LEXIS 67225, at *19-20 n.6 (S.D.N.Y. July 31, 2009).

¹³ Defendants’ reliance on *N. Collier Fire Control & Rescue Dist. Firefighter Pension Plan & Plymouth Cnty. Ret. Ass’n v. MDC Partners, Inc.*, 2016 U.S. Dist. LEXIS 136929 (S.D.N.Y. Sept. 30, 2016) is misplaced, as in that case the issue was whether there even was misreporting of goodwill and the Court found that the plaintiffs had failed to plead any false and misleading statements with regard to those accounting allegations. 2016 U.S. Dist. LEXIS 136929 at *29-40. Here, the falsity of Defendants’ statements regarding Alere’s financial results is unquestioned.

internal controls in place to ensure that, domestically and internationally, Alere was complying with the law. Thus, the fact that fraudulent financial statements occurred with respect to foreign operations is fully consistent with Defendants' reckless disregard for the facts, based upon the totality of the facts alleged. *See, e.g., In re Lernout & Hauspie Sec. Litig.*, 208 F. Supp. 2d 74, 89 (D. Mass. 2002) (Saris, J.). This is particularly true where, as here, Defendants never previously disclosed that they were encountering any difficulty in complying with GAAP in Alere's overseas operations. *See, e.g., Aldridge*, 284 F.3d at 82; *see also In re Raytheon Sec. Litig.*, 157 F. Supp. 2d at 147 (omissions of fact from public statements concerning potential violations of GAAP also support a strong inference of scienter) (citing cases).

F. Red Flags and Widespread Knowledge at Alere Relating to Internal Control Failures Also Support a Strong Inference of Scienter

Defendants Nawana and Hinrichs repeatedly assured investors that Alere had sufficient internal controls in place and certified that they had designed internal controls to provide reasonable assurance regarding the reliability of Alere's financial reporting. *See* ¶¶210-212; *see also* ¶¶206-209 (describing internal control requirements under SOX and the Exchange Act). Defendants Nawana and Hinrichs have also admitted their personal familiarity with the Company's systems and processes. ¶244 (including the fact that the Company instituted a "monthly financial review with all the executives and all the finance leadership that probes much more deeply into the monthly results and what that means for the forecast.").

Defendants' false statements concerning the adequacy of Alere's internal financial controls are actionable if the persons signing the certification were severely reckless, a requirement which is satisfied "if the person signing the certification had reason to know, or should have suspected, due to the presence of . . . 'red flags' that the financial statements contained material misstatements or omissions." *In re Ebix, Inc. Secs. Litig.*, 898 F. Supp. 2d

1325, 1345 n. 9 (N.D. Ga. 2012) (citing *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1265 (11th Cir. 2006)).

Here, precisely such a red flag exists with respect to Alere's need to restate earlier financial statements because of an internal control weakness with respect to the reporting of deferred taxes. ¶ 229. Defendants' contention that there is no connection between that internal control weakness and the one which drove Alere's subsequent need to delay filing its 2015 Form 10-K and restate its previously reported quarterly results (*see* D.B. at 20) lacks merit. Specifically, Defendants ignore that the two internal control failures are connected because both arise from a lack of qualified personnel making the relevant accounting entries. *See* ¶¶ 227-229. Accordingly, the prior internal control failure constituted a "red flag" to Defendants, warning them of potential related problems with internal controls. *See, e.g., Varghese v. China Shenghuo Pharm. Holdings*, 672 F. Supp. 2d 596, 608 (S.D.N.Y. 2009) (the defendants' awareness of internal control weaknesses supports a strong inference of scienter).

Several former Alere employees confirm that knowledge of inadequate financial controls was widespread at Alere. *See* ¶¶ 41-44. Defendants contend that these allegations do not raise a strong inference of scienter because none of the Alere employees is alleged to have discussed internal financial control weaknesses with the Individual Defendants. *See* D.B. at 18. Such allegations, however, do give rise to a strong inference of scienter because, at a minimum, they represent circumstantial evidence of Defendants' knowledge of the underlying adverse facts. *See, e.g., Cabletron*, 311 F.3d at 30-31 (finding scienter based on allegations of former employees who provided specific, consistent allegations based on their personal knowledge); *Collier v. ModusLink Global Solutions, Inc.*, 9 F. Supp. 3d 61, 73 (D. Mass. 2014) (same).

Karpov v. Insight Enters., Inc., 2010 U.S. Dist. LEXIS 59771 (D. Ariz. Apr. 30, 2010), upon which Defendants rely here, is unavailing. In *Karpov*, the claims were asserted against KPMG, an outside auditor, and there were no plausible allegations that KPMG “had access to enough detail about [the company’s] business model to have knowledge of the [relevant facts].” *Id.* at *19. Here, in contrast, the Individual Defendants had complete and unfettered access to all the details of Alere’s business including that the same shortage of qualified personnel for reporting deferred taxes was affecting the Company’s ability to properly recognize revenues and, to this day, continues to plague Alere.¹⁴ *Karpov* is also distinguishable because it involved an action in which the material internal control weaknesses stood alone (*see Karpov*, 2010 U.S. Dist. LEXIS 59771, at *31) while here Alere’s material internal financial control weaknesses exist alongside, among other things, a motive and material misreporting of Alere’s financial results.¹⁵

¹⁴ Defendants inaccurately cite *In re ARIAD Pharm., Inc. Secs. Litig.*, 842 F.3d 744 (1st Cir. 2016) for the proposition that the First Circuit held that the PSLRA’s exacting standard of pleading scienter “must be satisfied” with allegations of either admissions or internal records or witnessed discussions suggesting the defendants were aware they were withholding vital information. *See* D.B. at 16. The First Circuit did not exclude other allegations suggesting knowledge or allegations of recklessness or motive. *See In re ARIAD*, 842 F.3d at 751. Defendants’ citation to *Local No. 8 IBEW Ret. Plan & Trust v. Vertex Pharms., Inc.*, 838 F.3d 76 (1st Cir. 2016) (D.B. at 16), is not on point because it involved the minutiae of reporting on drug test results where there was no reason to suspect any adverse information while here there were prior related known internal control weaknesses. *Cody v. Conformix, Inc.*, 2016 U.S. Dist. LEXIS 101754 (D. Mass. Aug. 3, 2016) (*see* D.B. at 17), similarly, involved the minutiae of day-to-day non-financial operations of a medical device company. Defendants cite *In re Magnum Hunter Res. Corp. Sec. Litig.*, 26 F. Supp. 3d 278 (S.D.N.Y. 2014) for the proposition that even if a defendant made false statements concerning internal controls and accounting errors, there was no scienter because the plaintiffs had not alleged that the defendants had the motive and opportunity to commit fraud. D.B. at 17-18. That case is plainly distinguishable from the facts of this case where the individual defendants were motivated to suppress the truth about Alere’s grossly deficient internal financial and operating controls in order to sell the Company and Abbott has alleged in its own lawsuit to terminate the merger that Defendants “blocked every attempt” by Abbott to assess issues at Alere.

¹⁵ Defendants’ reliance on *Roth v. OfficeMax, Inc.*, 527 F. Supp. 2d 791 (N.D. Ill. 2007) and *In re Turquoise Hill Res. Ltd. Sec. Litig.*, 2014 U.S. Dist. LEXIS 174096 (S.D.N.Y. Dec. 16, 2014) are likewise inapposite. *See* D.B. at 20. In *Roth*, the court held that *mere* allegations of GAAP violations, restatements of income, or statements regarding internal controls that are later proven to be false are not enough to establish that those making the statements committed securities fraud. *Roth*, 527 F. Supp. 2d at

G. Plaintiffs Allege a Strong Inference of Scienter with Respect to the FCPA Violations Which Are Tied to the Lack of Internal Financial Controls

Defendants' argument that Plaintiffs fail to allege a strong inference of scienter with respect to Alere's FCPA violations ignores that knowledge or reckless disregard of those violations is directly tied to an inadequate system of internal controls. In order for an Alere subsidiary or unit to provide improper and significant financial consideration or gifts to foreign government officials, that unit or subsidiary would necessarily need to have loose controls that an executive could easily manipulate, and lax enforcement over FCPA violations. Alere's disclosures demonstrate Defendants' knowledge that the anti-bribery provisions of the FCPA were a known material risk to the Company. *See, e.g.*, ¶ 218.

At the core of any corporate effort to prevent improper overseas payments is an adequate system of internal control. *See* 15 U.S.C. §78m(b) 2017. Thus, the Department of Justice and the SEC have made it clear that "[t]he payment of bribes often occurs in companies that have weak internal control environments." *A Resource Guide to the U.S. Foreign Corrupt Practices Act* at 40 (Criminal Division of the U.S. Department of Justice and the Enforcement Division of the U.S. Securities and Exchange Commission, Nov. 14, 2012).¹⁶

Here, Alere did not maintain such an adequate system of internal control, a fact which Defendants either knew or recklessly disregarded. *See* Point I.F. , *supra*. A former Alere National Sales Manager in India from 2013 through early 2015 described them as "very primitive." ¶232. He also stated that sales by Alere to state-level governments in India of

797-98. The court in *Turquoise* held that neither GAAP violations, accounting irregularities, the magnitude of a restatement or materially weak controls *alone* constitute scienter. 2014 U.S. Dist. LEXIS 174096, at *15-20. Here, there are numerous scienter allegations, including the Individual Defendants' motive to sell the Company and Abbott's own statements concerning Alere's efforts to hide the Company's numerous serious problems. ¶141.

¹⁶ Available at <https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/16/guide.pdf>.

diagnostic products were facilitated by “under the table” dealings between Alere distributors and government officials. ¶67. This former National Sales Manager explained that a potential supplier needed to qualify to supply products to the government based on price, and even though Alere did not offer the lowest price to the government, the government still very often selected Alere as the provider. *Id.* Further, Alere’s policies for ensuring adherence to anti-corruption laws were not open or transparent and most of Alere’s practices in India did not match global policies. ¶66.

These facts are supplemented by Defendants’ efforts to avoid a complete investigation by Abbott into the circumstances of any FCPA violations. *See, e.g., Collins & Aikman*, 524 F. Supp. at 492-93 (S.D.N.Y. 2007) (defendant’s effort to conceal facts via false documents and false statements create an inference that the defendant acted to defraud investors).¹⁷ For example, Alere attempted to prevent Abbott from interviewing Alere’s Director of Finance for its Indian operations. *See* ¶242. In addition, Alere refused for many months to provide Abbott with accounting records sufficient to enable it to investigate the Company’s violation of the FCPA (*see, e.g.,* ¶241) forcing Abbott to eventually file suit in Delaware in order to gain access to those

¹⁷ In attempting to deal with the allegations regarding the FCPA violations, Defendants employ the same strategy of separating out all of the scienter allegations rather than viewing them collectively as required. For example, Defendants cite to *Avid* for the proposition that a government investigation “‘is insufficient in and of itself’ to support an inference of scienter.” D.B. at 33, n.116 (citing *Avid*, 28 F. Supp. 3d at 114). Defendants failed to cite to the court’s holding in *Avid* that “[h]ere, the government investigation can be seen as one more piece of the puzzle, a series of circumstances that add up to a strong inference of scienter.” *Avid*, 28 F. Supp. 3d at 115. Likewise, Defendants’ citation to *In re Manulife Fin. Corp. Secs. Litig.*, 276 F.R.D. 87 (S.D.N.Y. 2011) is off-point as that case holds that the investigation at issue was the only allegation that raised an inference of scienter but did “not itself constitute a strong inference of scienter and [did] not sufficiently strengthen the other allegations.” 276 F.R.D. at 102. Indeed, Defendants belatedly admitted to at least six separate governmental investigations into the Company during the Class Period alone (¶236), and the myriad of these investigations gives rise to a strong inference of scienter. *See Avid*, 28 F. Supp. 3d at 115; *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F.Supp.2d 148, 168 (S.D.N.Y.2008) (including an investigation by the Department of Justice as one of the elements in the scienter analysis); *Enron*, 235 F.Supp.2d at 688 (including facts “unearthed in current investigations by the SEC” in the scienter analysis).

documents. ¶¶131-32. Alere agreed to settle Abbott's suit by having Alere turn over to Abbott "files about bribery probes of [Alere's] foreign operations and U.S. billing practices." ¶132. However, as Abbott has later stated, Alere has still not provided those documents to Abbott. *Id.* As Abbott has asserted, Alere continues to behave like a company that has "something to hide." ¶¶143, 240.

Defendants further argue that Plaintiffs' claims fail because the DOJ has not yet found that Alere violated the FCPA. D.B. at 33. However, for claims brought under the securities laws, "[i]t is the falsity of Defendants' statements which is critical," and the validity of the claims is "*not* dependant [sic] on the legality or illegality of Defendants' . . . activities" under the FCPA. *Halford v. AtriCure, Inc.*, 2010 U.S. Dist. LEXIS 144377, at *27-28 (S.D. Ohio Mar. 29, 2010). Misrepresentations about business practices are actionable, and there is no requirement to plead a violation of the underlying law. *See, e.g., In re Syncor Int'l Corp. Secs. Litig.*, 327 F. Supp. 2d 1149, 1161 (C.D. Cal. 2004) ("An FCPA violation is not required for a section 10b or Rule 10b-5 violation."), *aff'd in part, rev'd in part and remanded*, 239 F. App'x 318 (9th Cir. 2007); *see also In re Gentiva Secs. Litig.*, 932 F. Supp. 2d 352, 369 (E.D.N.Y. 2013) ("Whether or not [the D]efendants . . . actually violated various provisions of [Medicare] . . . are not issues for resolution at this [motion to dismiss] stage.") (citation omitted); *In re Cobalt Int'l Energy, Inc. Sec. Litig.*, 2016 U.S. Dist. LEXIS 5702 (S.D. Tex. Jan. 19, 2016) (denying the defendants' motion to dismiss even after the U.S. government dropped its FCPA investigation).

H. Defendants Admit that the Facts Giving Rise to INRatio's Recall Were Present as of December 2015

Defendants contend that Plaintiffs fail to allege any basis for Defendants knowing that a loss contingency for the INRatio products was necessary prior to July 2016 when Alere first disclosed those facts. D.B. at 23. However, Defendants ignore that the July 2016 disclosure was

made in the 2015 Form 10-K and related to a reserve taken in 2015, or ***at least eight (8) months earlier*** with respect to the INRatio products. Indeed, as Alere later disclosed in August 2016 with respect to INRatio’s recall, Alere recorded INRatio recall charges in 2015 because “the circumstances giving rise to the voluntary withdrawal [of the INRatio products] . . . existed ***as of December 31, 2015.***” ¶114. Alere recording the INRatio charge in the fourth quarter of 2015 demonstrates that the charge was probable and estimable during that period. ¶58. The unquestioned delay in disclosing the relevant facts supports a strong inference of scienter. *See, e.g., Akerman v. Arotech Corp.*, 608 F. Supp. 2d 372, 385 (E.D.N.Y. 2009).¹⁸

Defendants attempt to confuse the issue by arguing that the FDA only recommended the recall after receiving software enhancements at the end of 2015 which were deemed ineffective. D.B. at 25. This does not explain why it still took Alere several months in 2016 for the Company to withdraw the device. It also does not negate the fact that the \$38 million accounting

¹⁸ The authority upon which Defendants rely for the proposition that whether to establish a loss reserve and the amount of that reserve is a matter of judgment and that their judgment was held in good faith does not support Defendants’ position. In *Fait v. Regions Fin. Corp.*, 655 F.3d 105 (2d Cir. 2011) (*see* D.B. at 27) the plaintiff acknowledged that the defendant had increased its allowance for credit losses and publicly reported why they were being increased, but alleged that the amount of the increase was materially inadequate. *Fait*, 655 F.3d at 112-13. Here, Defendants failed to disclose any relevant loss contingency information regarding INRatio, let alone the underlying condition that necessitated the loss contingency. ¶191. Moreover, the Second Circuit held that because there was no “objective standard for setting loan loss reserves,” a plaintiff “must allege that defendant’s opinions were both false and not honestly believed when they were made.” *Fait*, 655 F.3d at 113. Here, Plaintiffs have alleged both. ¶¶186-191. Defendants’ reliance on *In re Hutchinson Tech. Inc. Sec. Litig.*, 502 F. Supp. 2d 884 (D. Minn. 2007) for the proposition that a loss exceeding the loss allowance ***does not in and of itself*** evidence knowledge that the allowance was false when made is likewise off-point (*see* D.B. at 27) as the Complaint contains multiple allegations as to why Defendants knew they should have established a loss reserve. ¶¶186-191. Defendants’ citation to *In re Apollo Grp., Inc. Sec. Litig.*, 2011 U.S. Dist. LEXIS 124781 (D. Ariz. Oct. 27, 2011) is off-point for the same reason as the plaintiff in that case provided only “conclusory assertions” that defendants knew they would be unable to collect certain amounts. *See* D.B. at 28.

reserve reflected in the 2015 Form 10-K belatedly filed in August 2016 unquestionably reflects the fact that the INRatio recall was probable by the end of 2015 but not promptly disclosed.¹⁹

Defendants also seek to undermine former Alere employees' statements demonstrating that the problems with INRatio were well known at Alere based on those witnesses not being accountants and not stating that they had any contact with Individual Defendants. D.B. at 27-28. However, Defendants ignore that the need to take an accounting reserve resulted from INRatio's failure as a product and the former employees attest to such failure. Other facts also support Plaintiffs' allegations. In particular, INRatio had the largest number of serious customer complaints of any Alere product. As Plaintiffs have alleged, the FDA had received more than 9,000 reports of malfunctions with INRatio products and more than 1,400 reports of injuries. ¶57. This was far higher than with similar devices, such as the market leader Roche's product, which had only 95 injury reports during the same period. ¶57. The high number of severe adverse incidents supports a strong inference of scienter. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 48-49 (2011). In addition, INRatio was already subject to partial recalls (¶52), which put Defendants on notice of the problems with the device. Defendants also ignore that given the importance of INRatio to Alere (¶¶59, 94), and the seniority of the former employees, constitutes further circumstantial evidence that the Individual Defendants knew about or recklessly disregarded, facts demonstrating that one of the Company's major products being a failure. *See, e.g., W. Palm Beach Police Pension Fund v. DFC Glob. Corp.*, 2015 U.S. Dist. LEXIS 77495, at *45 (E.D. Pa. June 16, 2015).

¹⁹ Defendants also attempt to insulate themselves by arguing that they had disclosed the risk of a recall. D.B. 24-25. The "cautionary language" cited by Defendants, however, failed to apprise the market that the problems with INRatio were actual existing fact, not just some hypothetical risk.

Defendants argue that it would not have been reasonable for Alere to attempt to fix the INRatio device if it understood that the product would need to be recalled. D.B. at 2. However, this assumes a fact not in the record, to wit, that there was any realistic hope that the attempted fix would work. In any event, Defendants would have been motivated to prevent disclosure of these issues until after the time the Company entered into the Merger Agreement because of the importance of INRatio to the Company's future business prospects. *See, e.g.*, ¶72. In addition, Defendants would have been motivated to prevent INRatio's withdrawal, an act which could be interpreted as an admission of fatal errors with the device, because it could lead to potential liability in pending lawsuits concerning INRatio (two of which were filed in early 2016, ¶91).

I. Plaintiffs Also Allege a Strong Inference of Scienter with Respect to Alere's Billing Practices

Defendants argue that Plaintiffs have failed to properly plead scienter with regard to the admitted failures in Arriva's billing procedures, asserting that the number of claims were too small to notice and that these were unintentional errors. D.B. at 34-35. This argument fails because it ignores that even if Defendants did not know of the individual billing errors, they still knew or recklessly disregarded that Arriva lacked sufficient internal controls to prevent precisely those billing errors (¶203), rendering the Arriva disclosures a foreseeable consequence of the Company's material weaknesses. In fact, Arriva had a long history of billing problems of which Defendants were aware or recklessly disregarded. ¶¶135-138.

This is particularly true in the context of Medicare billing because federal regulations leave little to no room for error. Thus, the Code of Federal Regulations governing revocation of Medicare enrollment status, billing privileges can be revoked with as few as three instances of abusive practices. ¶196. A decision by the Department of Health and Human Services noted that "even *one claim* for reimbursement for services to beneficiaries who were deceased is a

sufficient basis for CMS to revoke participation and billing status.” ¶198. Therefore, the fact that Arriva submitted 211 claims on behalf of deceased patients demonstrates the egregious nature of the Company’s lack of internal controls in another one of its critical business units. During the Class Period, Defendants failed to disclose this fact and the fact that CMS unilaterally shut off Arriva’s access to HETS, the tracking system used to determine Medicaid beneficiary eligibility. CMS’ November 2, 2016 decision denying Arriva’s request for reconsideration of the revocation of its Medicare eligibility demonstrates the seriousness of Arriva’s actions. Further supporting the strong inference that Defendants acted with scienter in their false statements about Arriva is the fact that, as with Alere’s FCPA violations, Abbott had to sue Alere for documents concerning the Company’s U.S. billing practices, and even after settlement of that action in which Alere agreed it would turn over such documents, it still has not done so. ¶¶131-32; 141.

The DOJ also issued a criminal subpoena to Alere on July 1, 2016 regarding the Company’s toxicology unit. ¶100. This subpoena requested records relating to Medicare, Medicaid and Tricare billings from 2010 at the Company’s pain management testing lab in Austin, Texas. *Id.* This DOJ subpoena followed the 2013 lawsuit filed by Horizon Blue Cross and Blue Shield filed a complaint against Alere and Alere Toxicology alleging that they committed insurance fraud by making false and fraudulent insurance claims for unnecessary tests. ¶61. The DOJ subpoena is a manifestation of a Company flying blind on internal controls.²⁰ Abbott recognized this when it sued to terminate the merger. It took note of the “two new criminal subpoenas” and included them in its list of “numerous negative developments” that

²⁰ Defendants take issue with a confidential witness’ statement about internal audits and suggest that Complaint is using the existence of those audits to show corporate negligence. D.B. at 31-32. Plaintiffs make no such allegation. Rather, what is important about those audits is that they found, *inter alia*, physicians had not consistently documented the medical necessity for tests Alere performed, did not support the medical claims, and did not receive documentation of medical necessity before billing was done. ¶64. These claims confirm the utter lack of controls at the Company.

were not “brought on by chance” and “can only be the result of a systemic failure of internal controls”. ¶141.

II. PLAINTIFFS PROPERLY ALLEGE CLAIMS ARISING FROM DEFENDANTS’ STATEMENTS RELATING TO THE ABBOTT MERGER

Abbott’s efforts to terminate the Merger Agreement contradict Defendants’ arguments that their statements relating to the merger were not materially false or misleading. Indeed, in their earlier motion to dismiss, Defendants proudly observed that “Abbott has not terminated the transaction or even sought a ruling that it may do so.” ECF No. 68 at 29. That is clearly no longer the case with Abbott having commenced actions to obtain key documents which Alere was withholding from being reviewed during the course of due diligence (*e.g.*, ¶¶131-32) and then, finally, suing to terminate the Merger Agreement. ¶¶140-43.

Defendants, switching gears, now claim that investors have been aware of the possibility that Abbott might seek to terminate the Merger Agreement since April 2016 and that Abbott’s actions since that time are simply “the materialization of the risks of which the market was already aware.” D.B. at 38. Here, Plaintiffs claim losses based on new material developments, including actions that Abbott took based on new material adverse disclosures about Alere during 2016, and based on new misconduct by Alere that Abbott learned of for the first time during 2016 (including Alere’s refusal to fully participate in due diligence and produce to Abbott the documents it was requesting). *See* ¶¶254-257 (loss causation allegations). Defendants also argue that the Court should ignore Abbott’s claims against Alere because Abbott is merely having buyer’s remorse after it agreed to purchase both Alere and St. Jude at the same time. D.Br. at 10. However, as Plaintiffs allege, the facts and the chronology of events do not support that assertion. ¶¶ 124-25.

Separate and aside from all the other facts supporting a strong inference of scienter, the timing of Alere's disclosure of its inability to comply with the deadline for filing its 2015 Form 10-K also supports a strong inference of scienter. Specifically, on February 1, 2016, the Company disclosed its merger with Abbott and filed a Form 8-K with respect to the Merger Agreement representing, consistent with Defendants' prior representations, that there were no significant deficiencies in financial internal controls. *See* ¶76.²¹ Yet, less than one month later, on February 26, 2016 in a Form 12b-25, the Company disclosed that it would be unable to timely file its annual report on Form 10-K followed by a disclosure on March 15, 2016 that the Company would be unable to file the Form 10-K within the customary extension period. ¶78. Such temporal proximity between false statements and the revelation of defendants' fraud bolsters a strong inference of scienter. *See, e.g., In re Salix Pharms., Ltd.*, 2016 U.S. Dist. LEXIS 54202, at *45 (S.D.N.Y. Apr. 22, 2016); *In re Bear Stearns Cos. Incc. Sec Deriv. & ERISA Litig.*, 763 F. Supp. 2d 423, 517 (S.D.N.Y. 2011) (scienter found where "JP Morgan discovered in the course of one weekend the overvaluation of assets and underestimation of risk exposure"); *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1224-25 (1st Cir. 1996) (four months between allegedly actionable prospectus and subsequent restructuring charge); *Gerber v. Bowditch*, 2006 U.S. Dist. LEXIS 27552, at *37-38 (D. Mass. May 8, 2006) (defendants took actions that were contradictory to their alleged false statements within weeks of making those statements).

²¹ *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981 (9th Cir. 2008), cited by Defendants (D.B. at 21, n.80) stands for the proposition that "Sarbanes-Oxley certifications are not sufficient, *without more*, to raise a strong inference of scienter." 552 F.3d at 1004 (emphasis added) (citation omitted). Here, as explained throughout, the SOX certification allegations do not stand alone.

CONCLUSION

For all the reasons stated above, Defendants' motion to dismiss should be denied in its entirety.²²

Dated: March 23, 2017

Respectfully submitted,

/s/ Adam M. Stewart

Edward F. Haber (BBO#215620)

ehaber@shulaw.com

Adam M. Stewart (BBO#661090)

astewart@shulaw.com

SHAPIRO HABER & URMY LLP

Seaport East

Two Seaport Lane

Boston, MA 02210

(617) 439-3939

Plaintiffs' Liaison Counsel

ABRAHAM, FRUCHTER & TWERSKY, LLP

Jeffrey S. Abraham (admitted *pro hac vice*)

jabraham@aftlaw.com

Lawrence D. Levit (admitted *pro hac vice*)

llevit@aftlaw.com

Matthew E. Guarnero (admitted *pro hac vice*)

mguarnero@aftlaw.com

One Penn Plaza, Suite 2805

New York, New York 10119

(212) 279-5050

(212) 279-3655 (fax)

Plaintiffs' Lead Counsel

**BERNSTEIN LITOWITZ BERGER &
GROSSMANN LLP**

Gerald H. Silk

Adam H. Wierzbowski

1251 Avenue of the Americas

New York, NY 10020

²² In an abundance of caution, should any of Plaintiffs' allegations fail for any reason, Plaintiffs respectfully request leave to amend pursuant to Fed. R. Civ. P. 15(a) which is to be freely granted. *See, e.g., Foman v. Davis*, 371 U.S. 178, 182 (1982) (cited in *Alharbi v. Beack*, 103 F. Supp. 2d 166, 167-68 (D. Mass. 2015) (Saris, J.)).

Tel.: (212) 554-1400

Fax: (212) 554-1444

Member of Plaintiffs' Executive Committee

ENTWISTLE & CAPPUCCI LLP

Vincent R. Cappucci

Robert N. Cappucci

Heather Sertial

299 Park Avenue, 20th Floor

New York, NY 10171

Telephone: (212) 894-7200

Fax: (212) 894-7272

Member of Plaintiffs' Executive Committee

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on March 23 2017.

/s/ *Adam M. Stewart*
Adam M. Stewart